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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,106	11/25/2003	Nasr-Eddine Djennati	ISA-003.01	4845
63767	7590	06/27/2007		
FOLEY HOAG, LLP PATENT GROUP (w/ISA) 155 SEAPORT BLVD. BOSTON, MA 02210-2600			EXAMINER WEST, PAUL M	
			ART UNIT 2856	PAPER NUMBER
			MAIL DATE 06/27/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/722,106

Applicant(s)

DJENNATI ET AL.

Examiner

Paul M. West

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 May 2007 has been entered.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-7, 9, 10, 13, 18, 19, 22-27, and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Goddard (EP 0400847 A2).

2. As to claims 1, 5-7, 9, 10, and 22, Goddard teaches a device for determining the coagulation state of a sample comprising: a chamber 23 defining a volume which serves as a filling chamber for receiving a sample of blood to be analyzed; a filling device 22 for filling the chamber 23; a spherical particle 29 disposed within the volume wherein the particle 29 is made of steel, which is ferromagnetic and experiences a force when placed in a magnetic field; a means 30 for applying a magnetic field to a part of

the volume 23; and a Hall Effect sensor operative to detect the time-dependent movement of the particle (Col. 3, lines 3-6); and a processor 33 configured to determine the coagulation state of the sample based on the time-dependent movement of the particle (Col. 6, lines 28-31).

3. As to claims 2-4, Goddard teaches the device having a display 2 which displays a clotting time, a value which may be correlated with a disturbance in hemostasis (Col. 6, lines 57-58; Col. 7, lines 1-3).

4. As to claims 13, Goddard teaches the particle comprising steel with a thromboplastin reagent coating (Col. 3, lines 52-55).

5. As to claims 18 and 19, Goddard teaches the interior walls of the chamber being coated with thromboplastin (Col. 3, lines 49-55).

6. As to claim 23, Goddard teaches the device comprising circuitry for measuring the time elapsed from introduction of a sample until a coagulation state is reached (Col. 3, lines 22-34).

7. As to claim 24, Goddard teaches a control means 33.

8. As to claim 25, Goddard teaches a device for determining the coagulation time of a sample, the device comprising: a container defining a chamber 23 for holding a quantity of the sample, wherein the chamber holds a particle 29; a magnetic device 30 co-operating with the container 23; a magnetic field which causes the particle 29 to migrate to and fro within the chamber 23 through the sample; and a magnetic field sensor operative to detect the time-dependent movement of the particle (Col. 3, lines 3-6).

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9. As to claims 26 and 27, Goddard teaches the chamber having a volume of less than 20 $\mu$ L which includes volumes less than 5 $\mu$ L (Col. 2, lines 25-26).
10. As to claim 28, Goddard teaches the device comprising a means 3 for heating the chamber.
11. As to claim 29, Goddard teaches the chamber being formed in a disposable support strip 21 which is removable from the device (Col. 5, lines 42-43).
12. As to claim 30, Goddard teaches a method for determining the coagulation state of a sample comprising: providing a sample containing a particle 29 comprising a material (steel) which experiences a force when placed in a magnetic field; applying a magnetic field to the sample by means of electromagnet 30; and using a magnetic field sensor to detect the time-dependent movement of the particle 29 (Col. 3, lines 3-6) to determine the coagulation state of the sample.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 11, 12, and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goddard (EP 0400847 A2).
15. As to claims 11 and 12, Goddard does not teach the particle having a size between 2 and 500 $\mu$ m or between 2 and 20 $\mu$ m, however Goddard does teach the

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particle being of a specific size base on the size of the sample and of the chamber being used. It would have been obvious to one of ordinary skill in the art to change the size of the particle based on the size of the other equipment being used and the spacing of the magnet from the chamber, and further it has been held that a change in the size of a prior art device is a design consideration within the skill of the art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955).

16. As to claims 15-17, Goddard does not teach using a specific strength of magnetic field, however it would have been obvious to one of ordinary skill in the art to use a magnetic field strength between 10 and 20 mT or any reasonable magnetic field strength that is capable of moving the particle before coagulation but causes substantially less movement after coagulation because this is the only way the device can work.

17. Claims 8, 14, 20, 21, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goddard in view of Oberhardt et al. (5350676).

18. As to claim 8, Goddard teaches all of the limitations as set forth above but does not teach the filling device comprising a capillary. Oberhardt et al. teach a coagulation measuring device with a filling chamber 14 and filling device which comprises a capillary 26 (Col. 8, lines 41-43). It would have been obvious to one of ordinary skill in the art to use a capillary as taught by Oberhardt with the device of Goddard because it would allow a sample to be pulled into the filling chamber while preventing the sample from easily spilling out of the chamber.

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19. As to claim 14, Goddard does not teach having more than one particle disposed in the volume. Oberhardt et al. teach a coagulation measuring device which moves multiple particles (Col. 6, lines 1-3) back in forth in a sample using a changing magnetic field. It would have been obvious to one of ordinary skill in the art to use multiple particles as taught by Oberhardt with the device of Goddard because multiple particles would reduce statistical error by providing data at multiple spatial points within the sample.

20. As to claims 20 and 21, Goddard does not teach using two spaced apart electromagnets being alternately activated, but rather teaches one electromagnet which is alternately turned on and off. Oberhardt et al. teach using two magnets 400, 196 spaced apart one of which is an electromagnet 196 which alternately turns on and off. It would have been obvious to one of ordinary skill in the art to use two spaced apart magnets as taught by Oberhardt with the device of Goddard because two magnets would provide more control over the movement of the particle in opposite directions. It would have been further obvious to use two electromagnets because an electromagnet has more versatility than a permanent magnet, as it's intensity can be varied and it can be switched on and off.

21. As to claim 31, Goddard teaches a method of determining the coagulation time of a sample comprising: causing a particle 29 comprised of material (steel) which experiences a force when placed in a magnetic field to move through the sample; using a magnetic field sensor to detect the time-dependent movement of the particles (Col. 3, lines 3-6); and noting as the coagulation time, an instant at which changes in the

properties of the sample reduce the movement (Col. 3, lines 20-28). Goddard does not teach using multiple particles. Oberhardt et al. teach a coagulation measuring device which moves multiple particles (Col. 6, lines 1-3) back in forth in a sample using a changing magnetic field. It would have been obvious to one of ordinary skill in the art to use multiple particles as taught by Oberhardt with the device of Goddard because multiple particles would reduce statistical error by providing data at multiple spatial points within the sample.

22. Claims 32-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oberhardt et al. in view of Goddard.

23. Regarding claims 32-36, Oberhardt teaches a chamber 24 defining a volume for receiving a sample to be analyzed; magnetic particles disposed in the chamber, wherein the ratio of the chamber volume to particle volume is greater than 30 (see Fig. 2); a means 196 for applying a magnetic field to the chamber causing the particles to move to and fro in the chamber; and a sensor which detects the movement of the particles in order to determine a coagulation state and time of the sample. Oberhardt does not teach using a magnetic field sensor to detect the time-dependent movement of the particles, or a processor in order to determine the coagulation state and time of the sample. Goddard teaches using a Hall Effect sensor operative to detect the time-dependent movement of the particle (Col. 3, lines 3-6); and a processor 33 configured to determine the coagulation state of the sample based on the time-dependent movement of the particle (Col. 6, lines 28-31). It would have been obvious to one of



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ordinary skill in the art to combine the teachings of Goddard with those of Oberhardt because the use of a Hall effect sensor allows the chamber to be made of materials other than transparent ones as with Oberhardt's design, and the use of a processor allows sample data to be easily and efficiently recorded and stored.

24. Regarding claims 37-40, Oberhardt teaches a method comprising: subjecting a blood mixture to an oscillating magnetic field, wherein the mixture comprises magnetic particles (Col. 4, lines 8-12); and determining the coagulation time of the sample based upon a reduced movement of the particles (Col. 4, lines 41-45). Oberhardt does not teach using a magnetic field sensor to detect the time-dependent movement of the particles. Goddard teaches using a Hall Effect sensor operative to detect the time-dependent movement of the particle (Col. 3, lines 3-6). It would have been obvious to one of ordinary skill in the art to combine the teachings of Goddard with those of Oberhardt because the use of a Hall effect sensor allows the chamber to be made of materials other than transparent ones as with Oberhardt's design.

### ***Response to Arguments***

25. Applicant's arguments filed 30 May 2007 have been fully considered but they are not persuasive.

26. Applicant has argued that Goddard does not teach using a Hall effect sensor to monitor the time-dependent movement of a particle as it moves to and fro within a magnetic field. However, Goddard clearly teaches moving a particle within a magnetic field and monitoring its movement. Applicant has argued that detecting the return of the

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particle to its resting position is not a detection of movement. However, repeatedly detecting a particle returning to a position after it was absent from that position, as is done by Goddard, is monitoring movement of the particle. The return of the particle to a position is a movement and this is one way Goddard discloses detection. Furthermore, Goddard discloses in Col. 3, lines 3-6, that the sensor may be a Hall effect transducer which detects changes in magnetic field. Changes in a magnetic field produced by the movement of the ferromagnetic particle of Goddard's apparatus would not happen instantaneously, but rather they would be continuous as the particle is moving toward the sensor and continuous as the particle is moving away from the sensor. Therefore, without conceding that the returning of the particle alone is not movement, the Hall effect transducer would necessarily detect a constant change in magnetic field as the particle approaches and moves away from the sensor and therefore would detect more than just the particle at one position.

### ***Conclusion***

27. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul M. West whose telephone number is (571) 272-8590. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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